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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/662,651	09/15/2003	Bart De Strooper	2676-6086US	2464

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EXAMINER	
LYLES, JOHNALYN D	

ART UNIT	PAPER NUMBER
1647	

DATE MAILED: 04/05/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/662,651	STROOPER ET AL.	
	Examiner	Art Unit	
	Johnalyn Lyles	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 December 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-43* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-43* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

JL

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-3 and 33-43, drawn to an isolated complex between presenilin and a type I transmembrane protein and a receptor in an *ex vivo* system having binding activity for a type I transmembrane protein or binding activity for presenilin, classified in class 530, subclass 402.

II. Claims 4-7, drawn to an isolated binding domain of an isolated complex between presenilin and a type I transmembrane protein consisting essentially of the first transmembrane domain of presenilin, classified in class 530, subclass 402.

III. Claims 8-11, drawn to an isolated binding domain of an isolated complex between presenilin and a type I transmembrane protein consisting essentially of the last eight carboxyterminal amino acids of presenilin, classified in class 530, subclass 402.

IV. Claims 12-15, drawn to an isolated binding domain of an isolated complex between presenilin and a type I transmembrane protein consisting essentially of a sequence of amyloid precursor protein having presenilin binding activity, classified in class 530, subclass 402.

V. Claims 16-19, drawn to an isolated binding domain of an isolated complex between presenilin and a type I transmembrane protein consisting

essentially of a sequence of telencephalin having presenilin binding activity, classified in class 530, subclass 402.

VI. Claims 20-29 and 32, drawn to a method of identifying at least one compound capable of modulating the interaction between a complex of presenilin and a type I membrane protein or a method for producing a pharmaceutical composition, classified in class 530, subclass 402.

VII. Claims 30-31, drawn to a compound, classified in class 514, subclass 2.

The inventions are distinct, each from the other because:

Inventions I and Inventions II-V are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because the isolated complex between a presenilin and a type I transmembrane (TM) protein or the receptor does not require the isolated binding domain of Invention II, III, IV, or V (subcombinations). The isolated complex between a presenilin and a type I TM protein or the receptor can comprise any one of the isolated binding domains of Inventions II-V (Chen and Schubert, Exp. Rev. Mol. Med., 21 August, 2002). The subcombinations have separate utility, such as a component of another complex than the complex or receptor protein claimed. For example, the isolated binding domain consisting

essentially of the first TM domain of presenilin can be a component in the complex between presenilin and rab GDP dissociation inhibitor (Scheper et. al., Hum Mol Genet. 2000 Jan 22, 9(2):303-10); the isolated binding domain consisting essentially of the last eight carboxy terminal amino acids of presenilin can be a component in the complex between presenilin and Bcl-X(L), an anti-apoptotic member of the Bcl-2 family (Passer et. al., J Biol Chem. 1999 Aug 20, 274(34):24007-13); the isolated binding domain consisting essentially of a sequence of amyloid precursor protein (APP) can be a component in the complex between presenilin and APP as shown by Xia et. al. (PNAS. 1997, 94(15):8208-8213); and the isolated binding domain consisting essentially of a sequence of telencephalin (TLN) can be a component in the complex between TLN and the C-terminal of the 65 amino acid mGluR7 as shown by Stowell and Craig (Neuron. 1999 Mar, 22(3):525-36).

Inventions II-V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the different inventions of Groups II-V are not disclosed as capable of use together and have different modes of operation. The inventions of Groups II-V are different binding domains and bind different substrates.

Inventions I-V and VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different

process of using that product (MPEP § 806.05(h)). In the instant case, the inventions of Groups I-V are materially different products and any of the products can be used in the method of Group VI as claimed.

Inventions I-V and VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the different inventions are unrelated and not disclosed as capable of use together and have different effects. The inventions of Groups I-V include an isolated complex between presenilin and a type I TM protein and isolated binding domains and each can be used to screen for compounds that modulate the interaction between presenilin and a type I TM protein. The invention of Group VII is a compound identified by a screening assay that modulates the interactions.

Restriction Groups

Furthermore, <u>for Applicant to be fully responsive</u> to the restriction requirement, applicant must select**, (1) protein or (1) compound** as set forth below as part of the restriction of the distinct inventions. This is not a species election.

If Applicant elects **<u>Invention I</u>**, then **select a protein from A or B**

A) an isolated complex comprising:

1) the first TM domain of presenilin

2) the last eight carboxy terminal amino acids of presenilin;

3) and the TM domain of said type I TM protein.

B) a receptor in an ex vivo system

1) the first TM domain of presenilin

2) the last eight carboxy terminal amino acids of presenilin;

3) and having binding activity for a type I TM protein.

If Applicant elects **Invention VII**, then **select a compound** from the group consisting of SEQ ID NO: 1-7 and 10.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, and the search required for each group is not required for the other groups because each group requires a different non-patent literature search due to each group comprising different products and/or method steps, restriction for examination purposes as indicated is proper.

Election of Species

This application contains claims directed to the following patentably distinct species of the claimed invention: presenelins and type I transmembrane proteins.

A. Presenilins

1. Presenilin 1
2. Presenilin 2

B. Type I transmembrane domain proteins

1. Telencephalin (TLN)
2. Amyloid precursor protein (APP)
3. Notch E-cadhein
4. Nicastrin

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1, 4, 8, 12, 16, 20-21, 26, 28-30, 32-33, and 37 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record

showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Conclusion

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain

dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Johnalyn Lyles whose telephone number is 571-272-3433. The examiner can normally be reached on M-F 8 am - 4 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on 571-272-0961. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

jdl

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PRIMARY EXAMINER
3-30-05